

morbidity and mortality. Airlock obstruction is especially insidious because it often goes un-noticed as a cause for discomfort when the patient's urine is unremarkable in appearance to suggest an obvious cause for obstruction (obstructing clots, heavy sediment, etc.). For example, intermittent airlock obstruction of a catheter leads to acute episodes of painful bladder distension, which can cause the unsupervised obtunded/disoriented/or senile patient to respond by traumatically removing his/her catheter with the balloon intact. The resulting urethral trauma, bleeding are risk factors for bacteremia, and nearly always lead to emergency medical/urologic consultation. Such patients are also at risk for developing a urethral stricture, a sequellae which alone can account for significant chronic morbidity, poor quality of life, and the expenditure of vast healthcare resources.

[0148] Despite increasing numbers of patients with chronic indwelling Foley catheters, product innovation to address this problem has generally been limited to bacteriostatic and bacteriocidal coatings, designed to impede bacterial migration along the catheter into the patient. Such coatings have generally been applied to the urethral catheters. However, the efficacy of these products to prevent UTI's during short-term catheter use has been inconclusive. Coated chronic indwelling catheters have failed to demonstrate efficacy to prevent UTI's, and this, combined with their significantly higher cost, has limited their use overall. Manufacturers of the one-piece drainage tubing and bag kits have also coated the drainage tubing with bacteriostatic and/or bacteriocidal agents. Such coated tubing products have not demonstrated the ability prevent UTI's.

[0149] All such coated catheters and drainage tubing units are limited by the fact that they are limited to attempting to stop the relatively inevitable ascension of bacteria along the catheter into the patient. The externalized catheter surface will always become contaminated with bacteria, and a proportion of these will frequently ascend to the level of the lower urinary tract. Thus, the critical issue becomes minimizing the likelihood that such ascending bacteria will lead to urinary tract infection. Indeed, once even a few bacteria ascend into the patient's bladder, the moment bladder residual urine becomes infected, the catheter's bacteriostatic or bacteriocidal coating becomes useless.

[0150] Blockage is problem frequently reported by more than half of outpatients with chronic urinary catheters. The literature suggests that the most common causes of catheter blockage include blood clots, sediment crystals and mucus within the catheter lumen. Air-locks could be the unrecognized primary cause of obstruction, while observed clots, mucus and sediment develop secondary to stasis caused by air-lock obstruction.

[0151] Catheter blockage accounts for many unscheduled office, evening and weekend visits, in addition to emergency room visits and visits by home nurses. A study examining after-hours home care nursing calls notes that 22 of 25 patients reported catheter-related problems.

[0152] Catheter urine outflow obstruction is harmful to the patient at many different and synergistic levels. In addition to predisposing the patient to infections, high intravesical pressures and large residual volumes directly and indirectly damage the upper and lower urinary tracts, alter local anatomy and diagnostic evaluations, and can lead to long term sequellae such as local scarring and stricture.

[0153] Within the bladder, the high intravesicle pressures that occur with bladder distension can defunctionalize blad-

der smooth muscle and cause acute urinary retention and chronic bladder dysfunction. Unless scheduled catheter removal for such patients occurs early during the day, subsequent urinary retention (which may develop several hours later) will necessitate after-hours or medical attention, adding to health-care costs. Acute bladder obstruction can also cause autonomic dysreflexia, committing the patient to a host of interventions and medical costs. Acute obstruction can also cause unstable bladder contractions, potentially prompting a confused patient to pull his/her catheter. Resulting trauma can lead to unnecessary diagnostic studies and associated costs, prolonged hospital stay, urethral strictures and/or bacteremia. An obstructed bladder can damage the upper tracts by limiting drainage, causing nephropathy. Resulting urinary stasis promotes nephrolithiasis, etc. If an indwelling ureteral stent is in place, then high intravesical pressure is transmitted through the patent stent to the upper tracts (FIG. 12), potentially causing nephropathy, hydronephrosis and scarring, urine stasis, etc. Our experiments show that the greater height of the curled segment, the greater the positive (obstructing) pressure within the proximal segment will be.

[0154] Unrecognized urine outflow obstruction from the upper and lower tracts can influence a patient's physical examination findings, and potentially lead to misdiagnosis. Intraoperatively, an unexpectedly distended bladder can lead to iatrogenic injury or misdiagnosis if the surgeon assumes that it is decompressed based on the fact that the catheter is in place. Catheter/drainage tube obstruction can also cause falsely low urine output, which will alter recorded fluid totals and mislead fluid management both intraoperatively and postoperatively. Suboptimal catheter drainage can create the symptoms and findings that lead mislead management toward the unnecessary administration of diuretics, fluids, analgesics, radiographic studies, etc. Such interventions can cause secondary adverse medical outcomes, such as the exacerbation of CHF, electrolyte imbalances, etc.

[0155] Another unexpected potential complication that can result from the high intravesical pressures caused by an obstructed catheter drainage system is leakage across "fresh" surgical wounds and anastomoses within the urinary tract. For example, if extravasation of urine at the vesico-urethral anastomosis after prostatectomy did occur, could this contribute to the development of bladder-neck contractures, given the highly sclerotic effects of urine on surrounding tissues? The inflammatory response to urine extravasated into the prostatic bed could also harm the exposed neurovascular bundles. Leakage across ureteral anastomoses would be expected to contribute to subsequent stricture formation. In sum, high bladder pressure due to catheter outflow obstruction can promote and prolong leakage from any surgical site within the urinary tract.

[0156] Studies of catheter drainage characteristics in pediatric and neonatal patient populations are currently underway at our institution. The narrower and often curled catheters frequently used with these patients suggests that the drainage tubing outflow may also be compromised.

## Conclusions

[0157] Traditional Foley catheter drainage does not consistently evacuate the urinary bladder. Increased residual urine likely contributes to nosocomial urinary tract infections, and many other associated problems with Foley catheter drainage. Our novel Foley drainage tubing system eliminates obstructive air-locks and help to optimally drain the urinary bladder.